REMARKS

This paper is responsive to the Office Action mailed June 30, 2006. Presently, all claims 1-53 stand rejected.

Claim 8 has been amended herein to correct a typographical error that caused a lack of proper antecedent basis with regard to the claim terminology. The embodiment described in claim 8 is illustrated, for example, in Figs. 8 and 9, wherein the dilator mechanism is designated by reference numeral 50. Dilator mechanism 50 includes dilator 52 and splittable introducer sheath 54. The inventive radially expandable introducer sheath is inserted into the lumen of the splittable sheath 54, and the splittable sheath is removed in conventional fashion. Claims 1-7 and 9-53 have not been amended.

Generally speaking, the present application is directed to a radially expandable introducer sheath, and to a method for inserting an article in a body opening utilizing a radially expandable introducer to enlarge the opening. The use of a radially expandable introducer sheath enables the medical professional to minimize the use of axial force when inserting a medical instrument through a pre-dilated opening in the patient's body.

Although the axial insertion of medical instruments through a pre-dilated hole in a patient's body is often accomplished in relatively straightforward fashion, in some instances, such as during a tracheostomy procedure, the medical professional may encounter difficulties when attempting such insertions. In these instances, the axially-directed force causes an undesired axial extension of the opening and increases the trauma experienced by the patient at the site. For example, during a tracheostomy procedure, the dilator is advanced into the trachea through the pre-dilated hole to open the trachea for introduction of a tracheostomy tube. The axial force exerted by the dilator may cause the trachea to collapse, thereby further increasing the trauma to the patient and preventing the establishment of proper ventilation. In order to minimize the possibility of a tracheal collapse, the physician must repeatedly insert and withdraw one or more dilators at incrementally greater distances and/or incrementally greater diameters

until the desired dilated diameter is obtained. This process can be very time-consuming at the very time that prompt action may be critical to the patient's well-being. Such problems are minimized with the use of a radially expandable introducer according to the present invention.

Section 102 rejections.

(a) Claims 29-30, 32, 33, 37-42 and 45 were rejected under 35 U.S.C. §102(b) as being anticipated by Heck (USP 6,083,207). Claims 29 and 41 are independent claims, and the remaining claims subject to this rejection are dependent, directly or indirectly, from claim 29 or 41.

Claim 29 is directed to a radially expandable introducer sheath for enlarging a percutaneous opening. The radially expandable sheath comprises a sheath body, the distal end of which comprises a folded portion when the sheath is in a non-expanded condition and an extended portion when the sheath is in a radially expanded condition. An insertion member is provided for holding the sheath body on the non-expanded condition. Claims 30, 32, 33, and 37-40 depend, directly or indirectly, from claim 29, and describe additional features of the radially expandable sheath.

Non-limiting examples of a sheath body and an insertion member according to the present invention are illustrated in Figs. 11-14. In the embodiment of Figs. 11 and 12, the distal-most end 13 of sheath body 12 is folded in an inward direction, and sandwiched between the distal end of the wire guide 60 and the insertion cannula 64. This is best shown in Fig. 12. In order to radially expand the sheath, a pusher mechanism 66 may be advanced in the distal direction by depressing knob 67, thereby releasing the sheath and permitting it to expand radially to dilate the body opening when a medical device, such as a tracheostomy tube, is inserted therethrough. The embodiment of Figs. 13 and 14 includes a dilator 70 combined with the release mechanism for the sheath.

The Heck patent teaches a partitioned hemostasis valve. The valve may be used in combination with a splittable introducer sheath to minimize bleeding

when a medical device, such as a pacemaker, is inserted into the body of a patient through the sheath. The sheath 20 utilized with the Heck device is not radially expandable from a non-expanded condition to an expanded condition in the nature of the claimed sheath. More particularly, sheath 20 does not include a folded distal end, nor has the Examiner identified any structure that meets this limitation. Furthermore, sheath 20 does not include an insertion member that holds the sheath in a non-expanded condition. The structure that the Examiner has identified as meeting this limitation appears to operate as an actuator for use in splitting the valve. It cannot fairly be considered an insertion member for holding a sheath in a non-expanded condition. In addition, it is noteworthy that the sheath used in the Heck device is a conventional splittable sheath 20. The sheath cannot be radially expanded without splitting the sheath, thereby destroying its very function as a sheath.

The inventive sheath, on the other hand, has a distal end that is expandable from a non-expanded condition to an expanded condition. However, such expansion does not destroy the ability of the sheath to function as such, and in fact, is implicit in the use of the sheath. The radial expansion of the sheath permits the body opening being dilated to be subjected to radial forces (as shown in Fig. 2), rather than axial forces (as shown in Fig. 1), in a manner to minimize the trauma experienced by a patient as the medical device is inserted through the sheath. To the contrary, radial expansion of the Heck sheath, if possible at all, would destroy the sheath by splitting it into two or more portions.

Applicants respectfully submit that the Heck device is far removed from the radially expandable sheath as claimed in claims 29, 30, 32, 33 and 37-40, and cannot anticipate these claims for failure to teach the elements described.

Independent claim 41 is directed to a radially expandable introducer sheath for use in the percutaneous insertion of an article in a body opening. The introducer sheath comprises a sheath body that may be aligned to provide an axial opening for passage of the article therethrough into the body opening, and a handle engaged with the sheath body. The handle includes an axial opening that

is aligned with the sheath body axial opening for passage of the article therethrough. The handle further comprises a perimetrical opening for removal of the sheath from the inserted article in the body opening.

The Examiner has cited valve separation system 16 of Heck as meeting the limitation of a handle having a C-shape. This is the same element that the Examiner previously cited with reference to claim 29 as meeting the limitation of the insertion member. It is unclear to Applicants how the same element can meet two widely different limitations of the claimed invention, and moreover, two elements (insertion member and handle) that are positioned at opposite axial ends of the inventive device. Additionally, Applicants submit that the valve separation system of Heck is not aligned with the axial opening of the sheath body in a manner to permit passage of an article therethrough. Rather, it is offset from the opening as shown in the figures. Furthermore, it does not include a perimetrical opening for removal of the sheath.

Applicants also point out to the Examiner certain irregularities in the present rejections. First, the Examiner has utilized features of USP 5,098,392 to support the anticipation rejections of at least some of the claims. If the Examiner is not convinced that the Heck patent clearly teaches the features alleged in the Sec. 102(b) rejections and that it is necessary to rely on USP 5,098,392, then the rejections should be presented under Sec. 103(a), and not under Sec. 102(b). Additionally, it is noted that claim 38 depends from claim 34, and claim 45 depends from claim 44. However, claims 34 and 44 are not subject to the Sec. 102(b) rejection. Therefore, since these claims (34, 44) are not anticipated by the Heck reference, then dependent claims 38 and 45 also cannot be anticipated. Clarification and/or removal of these rejections is requested.

(b) Claims 1, 6, 7, 11, 12 and 29-30 were rejected under 35 U.S.C. §102(e) as being anticipated by Gilson (6,514,280).

Prior to addressing the substance of the rejections, Applicants respectfully point out additional irregularities in this rejection. Claim 1 is an independent

claim directed to a method for inserting an article in a body opening. The method comprises the steps of: dilating the body opening; inserting a radially expandable introducer sheath into the dilated body opening; radially expanding the introducer sheath to enlarge said body opening by inserting the article through said expandable introducer sheath; and removing said introducer sheath while leaving the article in place in said body opening. Claims 6 and 7 depend, directly or indirectly, from claim 1. Claim 8 (not subject to this rejection) is also an independent claim. Claim 8 is directed to a method for percutaneously inserting an article in a body opening. Claims 11 and 12 depend, directly or indirectly, from independent claim 8. Since independent claim 8 is not subject to the Sec. 102(e) anticipation rejection, then claims dependent on claim 8, namely claims 11 and 12, cannot be anticipated by Gilson. Clarification and/or removal of these rejections is requested.

In addition to the foregoing, it is noted that Gilson is directed to a catheter for transvascular deployment of a radially compressible medical device. The catheter has a tubular outer body, within which is slidably mounted an inner tubular sheath. A guide wire is axially movable within the inner tubular sheath. The medical device to be inserted is mounted on the guide wire, and is collapsible within the sheath for deployment in the patient's body. The distal end of the tubular sheath is provided with circumferentially spaced-apart axial slits that extend in the proximal direction from the distal end of the sheath to sub-divide the distal end of the sheath into a number of tube sections. The tube sections are expandable when the sheath is pushed out the distal end of the body to deploy the medical device.

The Examiner's description of the relevance of the Gilson reference fails to clearly point out the portions of the reference that are relied upon to satisfy the requirements for anticipation. For example, claim 1 (a method claim) of the present application includes a step of dilating a body opening, and another step of radially expanding the introducer sheath to enlarge the body opening by inserting the article through the expandable introducer sheath. It is unclear where such

teachings are found in Gilson. With particular reference to the radially expanding step recited above, it is unclear how Gilson teaches enlarging the body opening by expanding an introducer sheath, nor how the Gilson device could be adapted for such use. Gilson teaches a sheath having an expandable distal end, and teaches the deployment of an expandable medical device via the sheath. Gilson does not teach a method wherein an expandable device is used to enlarge a body opening.

Claim 6 is dependent on claim 1, and includes the additional limitation of a release mechanism for allowing radial expansion of the sheath from a non-expanded condition to an expanded condition. Claim 7 is dependent on claim 6, and includes the additional limitation that the release mechanism comprises an insertion cannula positioned such that a distal end of the introducer sheath is maintained within the insertion cannula to retain the introducer sheath in the non-expanded condition.

Since these claims include the limitations of claim 1, as well as additional limitations, they are not anticipated for at least the same reasons that claim 1 is not anticipated. Furthermore, Applicants respectfully submit that Gilson fails to disclose a release mechanism, and most particularly, fails to disclose an insertion cannula structured such that the distal end of an introducer sheath is maintained within the cannula to retain the sheath in an unexpanded condition. The Examiner has not pointed out how the Gilson reference teaches such a release mechanism, and most particularly, a release mechanism as very specifically claimed in claim 7.

As stated above, claims 29 and 30 are apparatus claims directed to a radially expandable introducer sheath for enlarging a percutaneous opening. The sheath comprises a sheath body having a distal end comprising a folded portion when the sheath is in a non-expanded condition, and an extended portion when the sheath is in a radially expanded condition. An insertion member is provided for holding the sheath body in the non-expanded condition.

The catheter for transvascular deployment disclosed in Gilson is not utilized for enlarging a percutaneous opening. Neither the structure of the device illustrated in Gilson, nor the overall disclosure itself, suggests that it could be

utilized in this manner. Furthermore, Gilson does not disclose a sheath body having a distal end that is folded when the sheath is in a non-expanded condition, and extends when the sheath is radially expanded. Additionally, Gilson does not teach an insertion member for holding the sheath body in the non-expanded condition. Accordingly, Applicants respectfully submit that these rejections are overcome.

(c) Claims 1, 6, 7, 11, 12, 29-31 and 46-51 were rejected under 35 U.S.C. §102(e) as being anticipated by Laakso et al. (6,902,575).

The Laakso reference discloses an apparatus for inserting a self-expanding stent into a delivery device, and for delivering the stent into a body lumen. It does not teach a radially expandable introducer as claimed, nor does it teach a method of inserting an article wherein a radially expandable sheath is used to enlarge a body opening.

The Laakso apparatus comprises inner and outer tubes, and a capturing element slidably mounted on the inner tube and including a foldable sleeve. The capturing element is carried on the inner tube so that the distal end of the sleeve can extend beyond the distal end of the outer tube in an unfolded condition and be drawn into the outer tube by a blocking element. The stent has an end inserted into the sleeve and is drawn into the outer tube. The stent is deployed by inserting the apparatus into a body lumen to position the distal end of the tube adjacent the stent deployment site, and drawing the outer tube in a proximal direction relative to the stent, thereby releasing the stent from its radially constricted condition.

Applicant's respectfully submit that the Examiner's description of the relevance of the Laakso reference fails to clearly point out the portions of the reference that are relied upon to satisfy the requirements for anticipation. Included within this rejection are claims that relate to four separate independent claims, namely claims 1, 8 (claims 11 and 12 depend from claim 8), 29 and 46, each having a different claim scope. Notwithstanding the number of independent

claims of different scope involved in the rejections, the Examiner has explained the substantive basis for all claim rejections in a single sentence. The sentence purports to cite four reference elements from Laakso in support. However, three of these recited reference numerals cannot even be found in the Laakso patent (there are no reference numerals 208, 6 and 2 in Laakso). Applicants are simply unable to adequately respond to this rejection in the absence of more information from the Examiner. If this rejection is to be maintained, Applicants respectfully request that it be explained in greater detail in a subsequent non-final action so that Applicants may have an adequate opportunity to respond point by point.

Notwithstanding the foregoing, Applicants' representative points out that he has thoroughly reviewed the Laakso reference, and is unable to locate any teaching relating to a radially expandable introducer sheath that is inserted into a dilated body opening to enlarge the body opening by insertion of an article (such as a tracheostomy tube) through the sheath. More particularly, there is no discussion whatsoever in Laakso concerning the dilation or enlarging of body openings. Rather, Laakso teaches the radial expansion of a stent, not a method for enlargement of a body opening. Additionally, the method of claim 8 includes the use of a very specific dilator mechanism comprising an outer cannula and a dilator positioned within the cannula. No such dilator mechanism is disclosed (or can fairly be said to be inherent) in Laakso. Similarly, claim 46 recites an introducer sheath comprising a sheath body and an insertion cannula, AND a dilator for dilating the body opening. Applicants respectfully submit that such elements, and in particular a dilator, are not taught in Laakso. Dependent claims 47-51 likewise include numerous additional limitations that are not taught in Laakso. Claim 29 has been exhaustively discussed previously.

Sec. 103(a) rejections.

(a) Claims 1-6, 8-10, 13-28, 34-36 and 43-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Heck.

This rejection encompasses 30 claims, and includes various claims that depend from four different independent claims[1]. Some of the claims are method claims. Others are apparatus claims. All of the independent claims are of different scope. The Heck patent has been discussed above, and its shortcomings with regard to the present application have been cited. Most particularly, it has been pointed out that Heck is directed to the art of hemostasis valves, and utilizes a conventional splittable sheath in connection with her partitioned hemostasis valve. Heck fails to teach or suggest a radially expandable introducer sheath, and most particularly, a radially expandable introduce sheath that is used to expand a body opening to permit an article (such as a tracheostomy tube), to be passed therethrough for placement in the body. Heck is even further removed from the method claims of the present application (1-28). One skilled in the art would not peruse this reference when investigating a technique for enlarging a body opening for inserting an article therethrough. In the unlikely event that he did peruse the reference, no meaningful information would be gleaned from it that would permit the skilled artisan to perform the claimed methods.

The Examiner broadly states (without any apparent factual support or explanation) that all of the limitations of the claims subject to this rejection [30 claims, based upon four independent claims] are taught in Heck, with the exception of the material of the sheath body. Additionally, the Examiner acknowledged that Heck does not disclose all of the method steps, but stated that it would have been obvious to use Heck's apparatus for delivering an article into a body opening, and that doing so would carry out the steps as claimed.

In response, Applicants take issue with the Examiner's unsupported statement that the limitations are taught or suggested in Heck. It is the Examiner's burden to make a prima facie case of obviousness, which clearly requires that an explanation be provided (accompanied by factual support when necessary) of the basis for the rejection. Applicants respectfully submit that a prima facie case is clearly lacking. Furthermore, Applicants take issue with the

[1] Claims 2-6 depend from claim 1; claims 9, 10 and 13-28 depend from claim 8;

Examiner's statement that use of the Heck apparatus would carry out the steps claimed. Once again, Applicants respectfully request the Examiner to point out where Heck discloses or suggests the use of a radially expandable sheath to enlarge a body opening by inserting a medical article, such as a tracheostomy tube, through the sheath.

(b) Claims 52-53 were rejected under 35 U.S.C. §103(a) as being unpatentable over Laakso et al. in view of Heck.

Claims 52 and 53 depend from claim 50, which depends from independent claim 46. Claim 46 is directed to an introducer sheath system for use in the percutaneous insertion of an article in a body opening. The system comprises an introducer sheath comprising a sheath body and an insertion cannula. A distal end of the sheath body is foldable within an inner lumen of the insertion cannula when the sheath is in a non-expanded condition, and extendable beyond the insertion cannula to permit radial expansion of the sheath. A dilator is provided for dilating the body opening. The system may include a handle engaged with the sheath body. As claimed in claim 52, the handle may have a generally C-shaped configuration and comprise a circumferential opening. As claimed in claim 53, the handle may comprise a pivotable portion and a disengageable portion, in which the handle is selectively maneuverable between a closed position wherein the handle has a substantially continuous outer surface, and an open position. In the open position, the pivotable portion is pivoted and the disengageable portion disengages such that an opening is defined for permitting withdrawal of the introducer sheath from the inserted article.

According to the Examiner, Laakso discloses all of the limitations of the claims except for the presence of a handle as claimed, which is alleged to be supplied in Heck. Applicants respectfully submit that the cited references, either individually or in combination, do not teach or suggest an introducer sheath system as claimed. Applicants have previously discussed the Laakso reference

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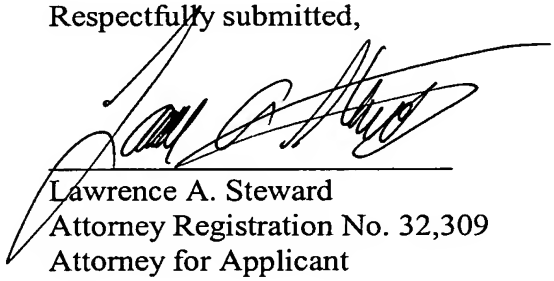
claims 34-36 depend from claim 29; and claims 43-44 depend from claim 41.

above. In addition to the comments previously presented, Applicants respectfully point out that neither Laakso nor Heck teaches or suggests an introducer sheath for enlarging a body opening as claimed, nor do they teach a dilator (as recited in independent claim 46) for dilating the opening. As stated above, independent claim 46 recites an introducer sheath comprising a sheath body and an insertion cannula, and a dilator for dilating the body opening. Applicants respectfully submit that such elements are neither taught nor suggested in the cited references.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of all claims 1-53 have been overcome, and that all of said claims are in condition for allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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